

- 8 -

REMARKS

In the application, Claims 3 and 11-20 are pending and rejected. The Examiner states that the arguments filed June 28, 2004 have been considered but are not deemed persuasive. Applicants now submit amendments and additional remarks in support of patentability.

The Examiner has maintained his prior position that the written description does not provide enabling disclosure as required under 35 U.S.C. §112, 1st paragraph. Specifically, the Examiner identifies the issue as the unpredictability as to what use that such displayed data is applied to. The example provided by the Examiner is that the some undefined calculation is used to define a position at which a third measure is displayed as a peak.

Claim 3 has been amended to eliminated reference to “calculation” since the term is somewhat misleading and appears to have misunderstood by the Examiner. Further language has been added to clarify the roles of the first, second and third values in terms of a three-dimensional coordinate system. Specifically, the inventive display is a graphic means for viewing the gene expression data by plotting a point on an X-Y plane, then creating a peak at that point corresponding to the quantity of the polynucleotide for those specific coordinates. No calculation occurs. Rather, a point is *plotted* in a plane according to an X-value, e.g., sequence identifier, and Y-value, e.g., sequence length. Then, the measured gene expression level for the corresponding fragment having that specific identifier and length is plotted along a Z-axis running through that point.

The invention relates to a way of visualizing the gene expression data that allows patterns to be recognized and comparisons to be made, particularly in a differential or temporal study. The predictable usage is that gene expression data is configured in a format that permits visual comparison and identification of patterns. The advantage is that a large amount of data, as one normally has with gene expression studies, can be handled and formatted in a visual configuration that permits patterns to be visually observed. The Examiner appears to be requiring that the displayed data have some predictable use in terms of a specific analytical result, e.g., a measurement or conclusion, rather than recognizing that it is the visual display itself that provides the advantages and useful results intended by the invention. It is well recognized in patent law that the manipulation of data to generate a display in itself qualifies as

- 9 -

patentable subject matter. (See In re Alappat, 33 F.3d 1526, 31 USPQ2d 1545 (Fed. Cir. 1994) (in banc).)

Quoting an excerpt from the Background of the Invention in the present application at page 5, line 31:

However, the very power of the gene expression profiling techniques poses a challenge to data handling methods and systems, to methods and systems for manipulating and analyzing the data, and to methods and systems for displaying the data so that it can be comprehended, studied and used. That is, the DNA sequences and gene monitoring techniques produce enormous amounts of data, so much so that new techniques are necessary for handling the data, for making it useful and for manipulating, analyzing and displaying it.

The problem to be addressed is a way to put massive amounts of gene expression data in a format that allows it to be observed and analyzed. The present invention comprises a means for generating a graphic display of gene expression data and related information. Such data, the means for obtaining such data, and the general interpretation of such data is already well known to those in the art. It is not necessary to specify a particular usage for the resulting graphic display in order for it to be useful. The usefulness of the claimed method is the ability to characterize the data in a format that allows researchers to visually assess large quantities of gene expression data to identify the existence of patterns, and to compare the profiles of different data sets to recognize changes in those patterns. One could look at endless printouts of numerical gene expression data, or enter the data into a computer classifier, to attempt to identify patterns in the data based solely on numerical values. This could take a long time and yield uncertain results, particularly when differential responses are observed. On the other hand, or in combination with numerical analysis, one could put the data in a format that allows it to be visualized as an image, not mere numbers in a list, where patterns can often be more easily discerned. This is the object of the present invention – to provide a method for visualizing gene expression data. The resulting display and its usage are completely predictable. Using the data elements and steps called for in the claims, a display will predictably be generated. That display can then be visually evaluated for use in identifying patterns in the data. Accordingly, there is nothing unpredictable about producing a graphic display that can be used to visual data.

- 10 -

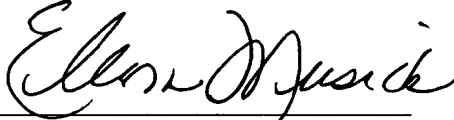
Claims 11-20 have been canceled and new claims 25-43 added to more clearly specify the subject matter of the invention. The new claims incorporate the additional elements discussed above relative to claim 3.

In view of the foregoing remarks, Applicants submit that all bases for rejection have been addressed and overcome such that the claims as now presented are enabled and allowable over the prior art. Accordingly, Applicants respectfully request that the Examiner withdraw all outstanding rejections and issue a notice of allowance for all claims now in the application.

It is believed that no fees are due for this response. Should it be determined that additional fees are owed, the Commissioner is authorized to charge such fees to Deposit Account No. 50-2075.

Respectfully submitted,

Dated: December 23, 2004

By: 
Eleanor M. Musick
Attorney for Applicants
Registration No. 35,623

PROCOPIO CORY HARGREAVES & SAVITCH LLP
530 B Street
Suite 2100
San Diego, California 92101-4469
Telephone: (760) 931-9703 (direct)
Facsimile: (760) 931-1155

Docket No. 4002-US (111944-000006)